IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

In re Namenda Direct Purchaser Antitrust Litigation

Case No. 1:15-cv-07488-CM (RWL)

MEMORANDUM IN SUPPORT OF FOREST'S MOTION IN LIMINE 10 TO EXCLUDE EVIDENCE AND ARGUMENT REGARDING THE POST-AGREEMENT SUBSEQUENT SALES HISTORY OF THE LEXAPRO AUTHORIZED GENERIC

WHITE & CASELLP

Counsel for Defendants Actavis plc, Forest Laboratories, LLC, Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd

TABLE OF CONTENTS

Argument		. 1
I.	The Court Should Exclude Reference to the Post-Agreement Subsequent Sales	
	History of the Lexapro Authorized Generic Because It Is Irrelevant and Risks	
	Confusing the Issues	.1
Conclusion		4

TABLE OF AUTHORITIES

	<u>Page(s)</u>
CASES	
Apotex, Inc. v. Cephalon, Inc., 255 F. Supp. 3d 604 (E.D. Pa. 2017)	2, 3
FTC v. Actavis, Inc., 570 U.S. 136 (2013)	3
Luitpold Pharm., Inc. v. ED. Geistlich Sohne A.G. Fur Chemische Industrie, No. 11-cv-681, 2015 U.S. Dist. LEXIS 123591 (S.D.N.Y. Sep. 16, 2015)	3
Valley Drug Co. v. Geneva Pharm., 344 F.3d 1294 (11th Cir. 2003)	2
STATUTES AND RULES	
Fed. R. Evid. 401	1, 4
Fed. R. Evid. 402	1, 4
Fed R Evid 403	1 4

The 2010 Lexapro Amendment shifted the manufacturing of the authorized generic version of the drug Lexapro from Forest to Mylan and secured from Mylan a commitment to continue selling the authorized generic for at least one additional year beyond what the initial 2005 agreement had required. Forest forecasted that this second-year commitment provided Forest with more than \$20 million of expected value. ECF No. 699-2, Defs.' Contentions ("Forest's Cont.") at 5-6.

Faced with this evidence, DPPs apparently plan to challenge the Lexapro Amendment by arguing that *actual* sales of the Lexapro authorized generic were lower than what Forest forecasted at the time of the Amendment nearly two years earlier. *See, e.g.*, ECF No. 699-1, Revised Pls.' Contentions ("DPPs' Cont.") at ¶ 152 ("Forest made no profits at all on authorized generic Lexapro in year two or any other time after Q4, 2012."); ECF No. 657, Pls.' Mem. of Law in Opp'n to Defs.' Mot. for Summ. J. at 30 (relying on post-settlement Lexapro sales); ECF No. 613, Pls.' Affirmative Statement of Material Facts in Opp'n to Forest's Mot. for Summ. J. at ¶ 281. DPPs seek to rely on subsequent sales history results to challenge Forest's contemporaneous forecasts about the value it expected from Mylan under the Amendment. *See* DPPs' Cont. at ¶ 152. But the law is clear that under the Rule of Reason, the reasonableness of an agreement is to be assessed *at the time that agreement was made*. The subsequent sales history of the Lexapro authorized generic should be excluded because it is both irrelevant and risks confusing the issues. *See* Fed. R. Evid. 401, 402, 403.

ARGUMENT

I. The Court Should Exclude Reference to the Post-Agreement Subsequent Sales History of the Lexapro Authorized Generic Because It Is Irrelevant and Risks Confusing the Issues

By way of background, Forest had a preexisting relationship with Alphapharm, and in 2005 entered into the original Lexapro Agreement. ECF No. 616, Defs.' Statement of

Undisputed Material Facts In Support of Defs.' Mot. for Summ. J. ("Forest's SOF") at ¶ 182. That 2005 Agreement required Forest to manufacture Lexapro, Alphapharm to market it, and Alphapharm to pay Forest sales royalties. Forest's SOF ¶¶ 184, 187, 189. In 2007, Mylan acquired Alphapharm. Forest's SOF ¶ 218. Forest and Mylan amended the Lexapro Agreement in 2010, which locked Mylan into one more year of the deal than the original agreement required and shifted manufacturing to world-class Mylan. Forest's SOF ¶¶ 255, 257, 264. Forest expected that this second year provided by the Lexapro Amendment would generate over \$20 million in value for Forest. Forest's Cont. at 5-6.

Turning to the argument, under the Sherman Act, the reasonableness of an agreement is assessed at the time the agreement is made. *See, e.g., Valley Drug Co. v. Geneva Pharm.*, 344 F.3d 1294, 1306 (11th Cir. 2003) ("[T]he reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into." (citing *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1207 (2d Cir. 1981)). Similarly, district courts have adopted this rationale in the *Actavis* context. *See, e.g., Apotex, Inc. v. Cephalon, Inc.*, 255 F. Supp. 3d 604, 611 (E.D. Pa. 2017) ("[T]he <u>Actavis</u> rule of reason analysis is focused on whether the settlements were reasonable at the time they were entered into").

DPPs and their expert have admitted that the agreement is judged at the time it was made. DPPs thus have even conceded that, "Forest's belief at the time it settled with Mylan" is the only "relevant issue" to the jury's determination of the value of the Lexapro Amendment. ECF No. 713, Mem. of L. in Opp'n to Forest's Mot. for Leave to Suppl. Its Expert Reports at 13. Likewise, DPPs' expert has opined that, "it doesn't matter whether [Forest's] estimates were right or not. What matters is that they were their estimates." Ex. 1, Sept. 29, 2017 Dep. of Einer Elhauge 145:6-8 (emphasis added).

Nevertheless, DPPs apparently intend to offer and rely on evidence not about the contemporaneous view of the agreement, but instead about the subsequent sales history of the Lexapro authorized generic to challenge the Lexapro Amendment. *See, e.g.*, DPPs' Cont. at ¶ 152 ("Forest made no profits at all on authorized generic Lexapro in year two or any other time after Q4, 2012."). But any after-the-fact assessment of actual sales of the Lexapro authorized generic does not bear on the reasonableness of the Lexapro Amendment at the time it was made, DPPs' burden of proof under *Actavis*, or any of DPPs' theories of causation or damages. *See Apotex*, 255 F. Supp. 3d at 611 ("Legal scholars and other courts presented with this issue concur with the ex ante interpretation of <u>Actavis</u>...."); DPPs' Cont. §§ V, VI (no contentions regarding causation or damages addressing the actual profitability of the Lexapro Amendment). That is because the central issue under *Actavis* is whether the brand was making a "large" and "unexplained" profit sacrifice because it believed its patent was weak, or rather was simply executing a "fair value" business transaction. *FTC v. Actavis, Inc.*, 570 U.S. 136, 156–57 (2013). Such assessments can be made only at the time of execution.

Moreover, even if evidence of the actual sales of Lexapro were of some minimally-probative value, that value would be substantially outweighed by the countervailing factors enumerated in Rule 403. Specifically, because only *pre-amendment* proof may be used to substantiate DPPs' claims, any *post-amendment* considerations would be "a sideshow that, even if relevant . . . would be confusing, misleading, and a waste of the jury's time." *Luitpold Pharm., Inc. v. ED. Geistlich Sohne A.G. Fur Chemische Industrie*, No. 11-cv-681 (KBF), 2015 U.S. Dist. LEXIS 123591, at *44 (S.D.N.Y. Sep. 16, 2015) (excluding deposition designations that had no probative value on the live issues for trial).

Post-amendment sales of the Lexapro authorized generic, nearly two years after the Lexapro Amendment was entered, are irrelevant under the relevant antitrust analysis. The Court should preclude DPPs from introducing evidence or argument that DPPs concede has no legal relevance to advancing their case at trial. Further, admitting such evidence would only confuse the issues, mislead the jury, and waste time, likely leading to a detour of the trial into the extraneous topics of real-world pricing and sales of generic versions of Lexapro.

CONCLUSION

For the foregoing reasons, the Court should exclude any evidence related to the post-amendment sales of generic Lexapro under Federal Rules of Evidence 401, 402, and 403.

Dated: May 24, 2019 WHITE & CASELLP

Martin M. Toto
Heather K. McDevitt
John H. Chung
Michael E. Hamburger
William H. Bave, III
Kristen O'Shaughnessy
Kevin C. Adam
WHITE & CASE LLP
1221 Avenue of the Americas

By: /s/ Martin M. Toto

New York, New York 10020 Telephone: (212) 819-8200

J. Mark Gidley Christopher M. Curran Eric Grannon WHITE & CASE LLP 701 Thirteenth Street, NW Washington, DC 20005 Telephone: (202) 626-3600

Heather M. Burke Eric E. Lancaster WHITE & CASE LLP

4

3000 El Camino Real 2 Palo Alto Square, Ste. 900 Palo Alto, CA 94306 Telephone: (650) 213-0300

Counsel for Defendants Actavis plc, Forest Laboratories, LLC, Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd.